UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,900	09/30/2003	Charles M. Buchanan	05015.0366U4	6139

23859 7590 12/13/2006

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,900	BUCHANAN ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 26-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 & 26-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 02 October 2006 wherein claims 1, 26, 11, 12, 19, 35, 36, 39, 43, 52, 53 and 56 have been amended. No new claim is submitted. Claims 2-22, 27-42, and 44-59 depends from amended claims.

Currently, claims 1-22 and 26-59 are pending in this application and under examination on the merits.

The following are new or modified rejections necessitated by Applicant's amendment filed 02 October 2006, wherein the limitations in all pending claims as amended now have been changed since claims 1, 26, 11, 12, 19, 35, 36, 39, 43, 52, 53 and 56 have been amended and claims 2-22, 27-42, and 44-59 depends from amended claims. The limitations in the amended claims have been changed and the breadth and scope of all claims have been changed. Therefore, all rejections from the previous Office Action, filed 07/27/2006, have been modified or withdrawn and are listed below.

Rejections Withdrawn

The rejection under 35 U.S.C § 112, second paragraph with respect to the phrase "100% (wt.) substituted" of claims 11, 12, 35, 36, 52 and 53 is withdrawn, since (wt.) limitation is deleted in said claims.

The following are new or modified rejections necessitated by Applicant's amendment filed 02 October 2006, wherein the limitations in all pending claims as amended now have been changed since claims 1, 26, 11, 12, 19, 35, 36, 39, 43, 52, 53 and 56 have been amended and claims 2-22, 27-42, and 44-59 depends from amended claims. The limitations in the amended claims have been changed and the breadth and scope of all claims have been changed. Therefore, all rejections from the previous Office Action, filed 07/27/2006, have been modified or withdrawn and are listed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, 19-22 and 26-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Uekama et. al. (U.S. Patent No. 5,904,929).

Uekama discloses medical devices (tablet and transdermal patch exemplified) comprising a polymer and an inclusion complex further comprising a pharmaceutically active agent and peracylated cyclodextrin. See examples. The exemplified pharmaceutically active agents are isosorbide dinitrate (freely soluble) and triamcinolone (sparingly soluble). Uekama et. al. discloses a

method in which the inclusion complex in an organic solvent is added onto a polymer film. (Column 7, lines 8-15). Example 4 shows pervaleryl-β-cyclodextrin-isosorbide dinitrate complex dissolved in ethanol solution added onto a polyethylene terephthalate film followed by the evaporation of ethanol. Example 13 in Uekama et. al. discloses the preparation of perbutanoyl-β-cyclodextrin complex with triamcinolone which was added to corn starch, microcrystalline cellulose and hydroxypropylmethylcellulose, mixed and tableted to form tablets. Starch, hydroxyproplymethylcellulose and microcrystalline cellulose are all polymers and are considered carriers since they are used in the formation of oral tablets. Furthermore, the mixing of the cyclodextrin-drug complex with said polymers to form a tablet is considered an "incorporation" into the carrier polymer. As such, Uekema anticipates said claims.

Response to Arguments/ Amendments

Applicants' arguments filed 02 October 2006 with respect to this rejection of claim 11 made under 35 U.S.C 102(b) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant has amended the instant claims to recite the term "carrier" in reference to polymer and added the phrase, "and the inclusion complex is incorporated into the carrier polymer."

Applicants' assert that Uekama et. al. does not disclose compositions where a polymer is used as a carrier and the inclusion complex is incorporated

into the carrier polymer. However, Uekama provides examples of compositions comprising a peracylated cyclodextrin complex with an active agent wherein the polymer component is clearly a carrier. For example, mixtures of trivaleryl-β-cyclodextrin with isosorbide dinitrate, which was further incorporated into a polyethylene terephthalate or cellulose/starch carrier.

Applicant contends that the Uekama compositions do not comprise an inclusion complex that is incorporated into the carrier. However, Applicant fails to point to a definition of "incorporated" that distinguishes the instant invention from the art. The examiner finds nothing in the specification that will preclude the type of incorporation described in Uekama et. al. As such, the incorporation of the inclusion complex as claimed is deemed to encompass the tableting of cyclodextrin-guest complex with carrier polymers described in Uekama et. al.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 102(b). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929).

Uekama teaches as set forth above. The reference does not exemplify the full range of guest molecules. However, the reference teaches a wide variety of such molecules, including fragrances. See col 4-6. The reference further teaches the use of a wide variety of additives known in the art for the preparation of the devices taught therein. See col 6, lines 35-41. It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the device(s) taught by Uekama using any of the guest molecules, including a fragrance molecule as expressly suggested by the reference with a reasonable expectation of success. It would be further within the scope of the artisan to use appropriate additives known in the art to prepare these products.

Response to Arguments

Applicants' arguments filed 02 October 2006 with respect to this rejection of claim 11 made under 35 U.S.C 103(a) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants argue that the polymers disclosed in Uekama et. al. are optional additives. Applicant further assert that upon reasonable consideration of Uekama et. al., the skilled artisan would find absolutely no suggestion or motivation to prepare and/or use composition whereby an inclusion complex is incorporated into a carrier polymer. As set forth above, Uekama et. al. provides

examples of peracylated cyclodextrin complex with active agents further comprising polymer carriers.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 103(a). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Rowe et. al. (U.S. Patent No. 6,616,650).

Uekama teaches as set forth above. The reference does not teach the full range of medical devices.

Rowe teaches the use of a balloon catheter coated with a composition comprising a therapeutic agent and a controlled release carrier, which may include a derivatized cyclodextrin. See col 2-3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a medical device such as a catheter using the acylated cyclodextrins taught by Uekama with a reasonable

expectation of success. In the absence of unexpected results, one of ordinary skill would be motivated to incorporate such a cyclodextrin because Uekama teaches that they have utility as a drug release agent.

Response to Arguments

Applicants' arguments filed 02 October 2006 with respect to this rejection of claim 11 made under 35 U.S.C 103(a) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants argue that the polymers disclosed in Uekama et. al. are optional additives. Applicant further assert that upon reasonable consideration of Uekama et. al., the skilled artisan would find absolutely no suggestion or motivation to prepare and/or use composition whereby an inclusion complex is incorporated into a carrier polymer. As set forth above, Uekama et. al. provides examples of peracylated cyclodextrin complex with active agents further comprising polymer carriers.

Applicants further argue that Rowe does not disclose cyclodextrin inclusion complex. Applicant is reminded that the rejection was based over two references. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800

F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The combined teachings of Uekama and Rowe renders the claims obvious.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 103(a). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Tuch et. al. (U.S. Patent No. 5,624,411).

Uekama teaches as set forth above. The reference does not teach the full range of medical devices.

Tuch teaches the preparation of drug eluting stents by adsorbing a solution of a drug solution onto the surface of a stent, which may be a bioadsorbable polymer, such as polyethylene terephthalate. See col 4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a drug-eluting stent to a polymer, such as polyethylene terephtalate, and apply a solution of an acylated cyclodextrin/drug inclusion complex to the surface. One of ordinary skill would reasonably expect success in

preparing such a product because Tuch had taught that polyethylene terephthalate is useful for the preparation of such a stent, and Uekama had taught that acylated cyclodextrins have utility for the controlled release of drugs and are successfully applied to a polyethylene terephthalate surface.

Response to Arguments

Applicants' arguments filed 02 October 2006 with respect to this rejection of claim 11 made under 35 U.S.C 103(a) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants argue that the polymers disclosed in Uekama et. al. are optional additives. Applicant further assert that upon reasonable consideration of Uekama et. al., the skilled artisan would find absolutely no suggestion or motivation to prepare and/or use composition whereby an inclusion complex is incorporated into a carrier polymer. As set forth above, Uekama et. al. provides examples of peracylated cyclodextrin complex with active agents further comprising polymer carriers.

Applicants argue that the polymers used in Tuch are not carrier polymer where an inclusion complex is incorporated therein, but are instead used to affix a drug to the surface of a stent. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended

use, then it meets the claim. The polymer by its ability to affix a drug to the surface of the stent, can act as a carrier. The applicants further argue that the amended claims recited the incorporation of an inclusion complex into a carrier polymer. One of ordinary skill in the art will view the limitation "incorporated into the carrier polymer" to include the application of an inclusion complex to a polymer surface.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 103(a). Therefore, said rejection is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-22 and 26-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uekama et al (US 5,904,929) in view of Ledger et. al. (U.S. Patent No. 5,865,792), further in view of Urtti et. al. (U.S. Patent No. 5,817,332).

Uekama teaches as set forth above. The reference does not teach the full range of medical devices.

Ledger teaches the preparation of the preparation of transdermal drug delivery devices using a wide variety of polymers. The reference further suggests the use of cyclodextrins in the drug composition. See particularly abstract and col 9. Urtti

demonstrates the applicability of cyclodextrins as drug delivery adjuvants in transdermal devices along with their use with a variety of polymers. See examples; col 4, lines 49-57; and col 5, lines 43-53.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the devices disclosed by Uekama using any polymers known in the art to have utility in preparing such a device. One of ordinary skill would reasonably expect success in using these polymers, particularly because Ledger had suggested their use in combination with a composition further comprising cyclodextrins with this application demonstrated by Urtti.

Response to Arguments

Applicants' arguments filed 02 October 2006 with respect to this rejection of claim 11 made under 35 U.S.C 103(a) of record in the previous Office Action have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicants argue that the polymers disclosed in Uekama et. al. are optional additives. Applicant further assert that upon reasonable consideration of Uekama et. al., the skilled artisan would find absolutely no suggestion or motivation to prepare and/or use composition whereby an inclusion complex is incorporated into a carrier polymer. As set forth above, Uekama et. al. provides examples of peracylated cyclodextrin complex with active agents further comprising polymer carriers.

The applicants argue that there is no disclosure, teaching or suggestion to incorporate an inclusion complex into a carrier, as recited in the amended claims. However, as noted in the previous office action, Ledger suggests the use of cyclodextrins in the drug composition, and discloses the use of a wide variety of polymers. The applicant further argue that "the only mention of a drug with a cyclodextrin is in a reservoir of an electrotransport device." The claims herein use the transitional phrase "comprising" which is an open transitional phrase, and thus does not exclude compositions present in electrotransport devices. The applicant asserts that "the entire disclosure of Ledger et. al. is based on the principle of electrotransport where an ionic drug having sufficient potential can be driven into a patient by an applied current." The applicant further argue that, "if one were to incorporate an ionic drug (or even an inclusion complex comprising an ionic drug" into a carrier polymer, the drug's ionic potential would likely be diminished by the surrounding carrier polymer." However, the disclosure of Ledger is not limited to ionic drugs. Ledger et. al. discloses the use of hydrocortisone, which is not considered and ionic drug. (Column 6, lines 37-48). As such, applicants' arguments were found unpersuasive.

Applicants' further argue that, "the polymer disclosed in Urtti et. al. is not a carrier polymer, as recited in the amended claims." The applicant further asserts that the drug and cyclodextrin in Urtti et. al. are encapsulated by a polymeric wall to form a reservoir. However, both Uekama et. al. and Ledger et.al. discloses the incorporation of cyclodextrin into carrier polymers. As noted above, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. The combined teachings of Uekama, Ledger and Urtti renders the claims obvious.

For the above stated reasons, said claims are properly rejected under 35 U.S.C 103(a). Therefore, said rejection is adhered to.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh C. Maier

Roy P. Issac
Patent Examiner
Art Unit 1623

Leigh C. Maier
Primary Examiner
Art Unit 1623